

REMARKS***Amendments to the Specification***

Applicants have amended the specification to correct an obvious error in accordance with MPEP 2163.07(a). Specifically, Applicants have corrected the concentrations of Na-acetate and imidazole buffer to read as 0.1 M N-acetate and 0.1 M imidazole. Applicants submit that one skilled in the art would not only recognize the existence of the error in the specification, but also the appropriate correction in view of the teachings of the specification. Specifically, Applicants direct the Examiner's attention to page 35, lines 20-22 in which the specification correctly recites that the concentrations of the additives are each 50 mM (after mixture of the buffer and enzyme solution in equal volume as clarified on page 36, lines 14-18). Accordingly, to achieve the 50 mM concentrations recited on page 35, lines 20-22 would require that the initial concentrations (prior to mixing equal volumes of buffer solution and enzyme solution) are 0.1 M N-acetate and 0.1 M imidazole, respectively. Accordingly, Applicants respectfully request entry of the amendments to the specification as set forth above.

Amendments to the Claims

Claims 60, 61, 62, 68, 70-72, 76 and 78-86 were pending in the instant application as of the issuance of the Office Action dated February 22, 2008. According to the foregoing amendments, claims 60 and 70 have been amended and claims 62 and 80-86 have been cancelled without prejudice to the prosecution of these claims in this or a subsequently filed application. Accordingly, after the amendments presented herein have been entered, claims 60, 61, 68, 70-72, 76 and 78-79 will remain pending in this application.

Support for the amendments to the claims may be found throughout the specification and in the claims as originally filed. Specifically, support for the amendments to claims 60 and 70 can be found throughout the specification at, for example, page 36, lines 3-25.

No new matter has been added by the amendments to the claims. The amendments to the claims and cancellation of certain claims should not be construed as an acquiescence to the validity of the outstanding rejections and were done solely in the interest of expediting prosecution and allowance of the claims. Applicants reserve the right to pursue the claims as previously pending and as originally filed in one or more further applications.

***REJECTION OF CLAIMS 60-62, 68, 70-72, 76 AND 78-86 UNDER
35 USC § 112, FIRST PARAGRAPH (WRITTEN DESCRIPTION)***

The Examiner has rejected claims 60-62, 68, 70-72, 76 and 78-86 under 35 U.S.C. § 112, first paragraph as allegedly “failing to comply with the written description requirement.”

Specifically, the Examiner is of the opinion that

[t]he Examiner acknowledge[s] the Applicants disclose a method comprising a crystallization of SEQ ID NO: 1 in the presence of bestatin using the crystallization condition as set forth on page 36, lines 3-19. However, this one examples [sic] does not sufficiently describe the claimed genus method of crystallizing LTA4 hydrolase (i.e., comprising SEQ ID NO: 1) under any condition. Applicants also acknowledge that crystallizing a protein is not routine and is ‘a major difficulties’... and the Applicants notes [sic] that the crystallization of instant example ‘were only obtained when the inhibitor bestatin was present in the crystallization set ups’... Applicants further argue, a method of crystallizing a protein having [an] amino acid sequence at least 90% identical to SEQ ID NO: 1 is not adequately described for the reasons below. Applicants argument that the instant specification provided sufficient correlation of the structure and functional relationship, wherein said structure is described in terms of the percent identity to a specifically disclosed amino acid sequence and the function is described in terms of the molecule as having an LTA4 hydrolase activity is irrelevant to the instant rejection because the instant written description rejection is about lacking correlation between the structure of LTA4 protein and the function of forming LTA4 protein crystal to be possessed by one skilled in the art... [B]eing able to make variants having 90% identical to SEQ ID NO: 1 is irrelevant to the instant written description rejection because the instant written description rejection is about lacking correlation between the structure of LTA4 protein variant having at least 90% identity to SEQ ID NO: 1 and the function of forming the crystal of said variant protein to be possessed by one skilled in the art.

Applicants respectfully traverse the foregoing rejection. Applicants submit that in view of their discovery of a method for crystallizing the LTA₄ hydrolase, and further in view of the teachings of the specification, one skilled in the art would appreciate that Applicants were in possession of the claimed invention at the time of filing of the present application.

Notwithstanding the foregoing, solely in the interest of expediting examination and in no way acquiescing to the validity of the Examiner’s rejections, Applicants have amended the pending claims in accordance with the Examiner’s recommendation, to specifically recite the crystallization conditions set forth in the specification, and further, have cancelled claims 80-86 directed to sequences of at least 90% identity to the amino acid sequence of SEQ ID NO:1, thereby rendering the foregoing rejection moot.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims as lacking written description under 35 U.S.C. § 112, first paragraph.

***REJECTION OF CLAIMS 60-62, 68, 70-72, 76 AND 78-86 UNDER
35 USC § 112, FIRST PARAGRAPH (ENABLEMENT)***

The Examiner has further rejected claims 60-62, 68, 70-72, 76 and 78-86 under 35 U.S.C. § 112, first paragraph as lacking enablement. Specifically, the Examiner is of the opinion that

the specification, while being enabling for a method comprising crystallization of SEQ ID NO: 1 in the presence of bestatin by the condition described on page 36, lines 3-19, that results in a crystal having the space group P21212 and the unit cell dimensions $a=67.59 \text{ \AA}$, $b=133.51 \text{ \AA}$, $c=133.51 \text{ \AA}$ and $\alpha=\beta=\gamma=90^\circ$; does not reasonably provide enablement for a method comprising crystallization of SEQ ID NO: 1 (or any protein having at least 90% identity to SEQ ID NO: 1) under any crystallization condition and/or in the presence of any compound...

[B]eing able to make and use variants having at least 90% identity to SEQ ID NO: 1 is irrelevant to the instant scope of enablement rejection because the instant scope of enablement rejection is based on unpredictability to make and use the full scope of claimed method comprising crystallization of SEQ ID NO: 1 (or LTA4 protein variant having at least 90% identity to SEQ ID NO: 1 under the same crystallization condition described on page 36.

Applicants respectfully traverse this rejection and submit that based on the teachings in Applicants' specification as well as the general knowledge available in the art at the time of the filing of the present application, one of ordinary skill in the art would be able to make and use the claimed invention using only routine experimentation. Indeed, Applicants submit that in view of their discovery of a method for crystallizing the LTA₄ hydrolase, and further in view of the teachings of the specification, one skilled in the art would be capable of practicing the claimed invention without undue experimentation. Notwithstanding the foregoing, solely in the interest of expediting examination and in no way acquiescing to the validity of the Examiner's rejections, Applicants have amended the pending claims in accordance with the Examiner's recommendation, to specifically recite the crystallization conditions set forth in the specification, and further, have cancelled claims 80-86 directed to sequences of at least 90% identity to the amino acid sequence of SEQ ID NO:1, thereby rendering the foregoing rejection moot.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims as lacking enablement under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In view of the foregoing remarks, reconsideration of the rejections and allowance of all pending claims is respectfully requested. If there are any remaining issues or if the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

The Commissioner is hereby authorized to charge any deficiency in the fees paid herewith, or credit any overpayment, to Deposit Account No. 12-0080, under Order No. PVZ-006USRCE, from which the undersigned is authorized to withdraw.

Dated: August 22, 2008

Respectfully submitted,

/Maneesh Gulati/

Electronic Signature for: Maneesh Gulati, Esq.

Reg. No. 60,963

LAHIVE & COCKFIELD, LLP

One Post Office Square

Boston, Massachusetts 02109

(617) 227-7400

(617) 742-4214 (Fax)

Attorney/Agent For Applicants